Amendments to the Drawings:

The attached sheets of drawings includes changes to Figure 1-22. These sheets replace the original sheets including Figures 1-22.

Attachment: Replacement Sheets

REMARKS

This Response is submitted in reply to the Office Action mailed on February 3, 2009. The Commissioner is hereby authorized to charge any fees which may be required or credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 112701-667 on the account statement.

Claims 1-44 are pending in the application. Claims 5-16 and 22-44 were previously withdrawn from consideration. In the Office Action, the Title is objected to; the Specification is objected to; Claims 1-4 and 17-21 are rejected; Claims 18 and 20 are objected to and the Drawings are objected to. In response, the specification and Claims 18, 19, 20 and 21 have been amended. These amendments do not add new matter. In view of the amendments and/or for the reasons set forth below, Applicants respectfully submit that the rejections should be withdrawn.

In the Office Action, the Oath/Declaration is objected to because the change in the spelling of Mohamed Ben Amor's name is not dated. In response, Applicants submit herein a new Declaration executed by Mohamed Ben Amor. Accordingly, Applicants respectfully submit that the objection to the Oath/Declaration be withdrawn.

In the Office Action, the Title is objected to because it is not descriptive of the elected invention, which is a polynucleotide. Without acquiescing to the merits of the Examiner's objection, and solely to expedite prosecution of the instant application, Applicants have amended the title to recite "POLYNUCLEOTIDE SEQUENCE ENCODING CYSTEINE PROTEASE FOR MODULATION OF COFFEE FLAVOUR PRECURSOR LEVELS IN GREEN COFFEE GRAINS." As amended, the title is descriptive of the elected invention. Accordingly, Applicants respectfully submit that the objection to the tile be withdrawn.

In the Office Action, the Drawings are objected to because there are two sets, both filed on December 8, 2005 and it is thus unclear which set is to be used; the legend for Figures 1A, 3A and 4A describes a lane "MW" which is not part of the Figures; there are two figures labeled 2A; the data in Figures 5, 6A and 12 is not visible; there are two figures labeled 6A; and the figures disclose sequences that are not identified by a sequence identifier number. Without acquiescing to the merits of the Examiner's objections, Applicants have submitted herewith a replacement set of figures that replaces the previously filed sets. The replacement figures contain lanes labeled as described in the specification, data that is clearly visible and sequence identifiers for any listed

sequence. Accordingly, Applicants respectfully submit that the objection to the figures be withdrawn.

In the Office Action, the Specification is objected to for disclosing sequences that are not identified by a sequence identifier number (SEQ ID NO:). Without acquiescing to the merits of the Examiner's objection, Applicants have amended the specification to include sequence identifier numbers for disclosed sequences. These sequences have also been added to a substitute sequence listing provided herein. Accordingly, Applicants respectfully submit that the objection to the specification be withdrawn.

In the Office Action, Claims 18 and 20 are objected to for "non-native recombinant DNA...", which would be better stated as "recombinant DNA...". Without acquiescing to the merits of the Examiner's objection, and solely to expedite prosecution of the instant application, Applicants have amended Claims 18 and 20 to recite "recombinant DNA." Accordingly, Applicants respectfully submit that the objection to Claims 18 and 20 be withdrawn.

In the Office Action, Claims 1-4 and 17-21 are rejected under 35 U.S.C. § 101 and 35 U.S.C. 112, first paragraph, because the claimed invention lacks patentable utility. In particular, the Office Action has alleged that the specification fails to teach a specific and substantial function for the protein set forth by SEQ ID NO: 2, as encoded by SEQ ID NO: 1, because the family of cysteine proteases is a large and variable family of enzymes. Applicants respectfully disagree with and traverse the rejection for at least the reasons set forth below.

MPEP 2107.I.A provides that "[a] 'specific utility' is specific to the subject matter claimed and can 'provide a well-defined and particular benefit to the public'." Additionally, MPEP 2107.01.I.B makes clear that to satisfy the "substantial utility" requirement, an asserted use must show that the claimed invention has a significant and presently available benefit to the public.

Applicants respectfully submit that the claimed polynucleotide (SEQ ID NO: 1) has a specific and substantial utility because it encodes a cysteine protease of SEQ ID NO: 2 (CcCP-1) that is expressed in green coffee beans where it may cleave storage proteins in the bean and thus contribute to the bean's flavor and/or aroma profile (specification at paragraphs [0004]-[0008]). Thus, Applicants disclosure provides a well-defined and presently available benefit to the public-modulation of coffee flavor and/or aroma.

Moreover, Applicants submit that the above asserted utility of the protein encoded by the claimed polynucleotide, as a cysteine protease is credible. Applicants note that the Office Action has not set forth any evidence to contradict that SEQ ID NO: 2 (CcCP-1) is not a cysteine protease. In fact, the instant specification provides that the polypeptide of SEQ ID NO: 2 has a high level of sequence similiarity to several known cysteine proteases (see, e.g., Figure 2). Further, as shown by GenBank protein domain analysis (Exhibit A attached), the polypeptide of SEQ ID NO: 2 comprises a conserved active site. This active site is comprised of a histidine and cysteine diad and is characteristic of a cysteine protease. Thus, sufficient and credible biological evidence exists that the claimed polynucleotide encodes a cysteine protease.

As the Examiner is certainly aware, it is not necessary that Applicants prove the biological mechanism by which the claimed polypeptide operates in order to show utility. All that is required is that the claimed isolated peptide has a utility as has been disclosed throughout the specification. Thus, Applicants submit that a sufficient showing of utility has been made in the present specification and requests that the rejection under 35 U.S.C. § 101 and the associated rejection under § 112 be reconsidered and withdrawn.

In the Office Action, Claims 19-21 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Office Action alleges that the phrase "a cell" renders claims 19-21 indefinite. Without acquiescing to the merits of the rejection, and solely to expedite prosecution of the instant application, Applicants have amended claims 19-21 to recite that the "cell" is an "isolated host cell." Accordingly, Applicants respectfully request that the rejection of claims 19-21 be withdrawn.

In the Office Action, Claims 1-4 and 17-21 are rejected to under 35 U.S.C. § 112, first paragraph, because the specification does not reasonably provide enablement for any polynucleotide encoding a polypeptide having at least 70% or 85% homology to SEQ ID NO: 2 or any polynucleotide comprising SEQ ID NO: 1 or comprising a sequence encoding SEQ ID NO: 2, wherein the polynucleotide encodes a cysteine protease. In particular, the Office Action asserts that the specification does not establish regions of the protein structure which may be modified without affecting the desired activity, the general tolerance of the desired activity to modification, a rational and predictable sheme for modifying any residues with an expectation of

obtaining the desired biological function and the specification provides insufficient guidance as to which of the infinite possible choices are likely to be successful. Applicants respectfully traverse this rejection for at least the reasons set forth below.

Any analysis of whether a particular claim is supported by the disclosure in an application requires a determination of whether that disclosure, when filed, contained sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention. The standard for determining whether the specification meets the enablement requirement is whether the experimentation needed to practice the invention is undue or unreasonable. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). In fact, a patent need not teach, and preferably omits, what is well known in the art. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991).

Applicants respectfully submit that polynucleotides encoding a polypeptide with at least 70% or 85% homology to SEQ ID NO: 2 are enabled by the instant specification. Procedures and methods for identifying variant polynucleotides that retain the activity of the parental nucleotide are commonly practiced by a skilled artisan (i.e. advanced degree in biotechnology). As shown in Exhibit A (attached), one of skill in the art can readily identify the region of the polynucleotide that encodes for the catalytic active site of SEQ ID NO: 2. Such knowledge allows a skilled artisan to modify a parental nuclic acid without undue experimentation while retaining its catalytic activity. charactersit cof a cysteine protease. Moreover, it is appreciated by one having ordinary skill person that a polynucleotide encoding a specific polypeptide may differ from a given sequence according to the Wobble hypothesis, in that nucleotides are exchanged that do not lead to an alteration in the amino acid sequence. In view of this, nucleotide sequences that exhibit a nucleotide exchange leading to an alteration of the amino acid sequence such that the functionality of the resulting polypeptide is not essentially disturbed can fall within the purview of the present claims. Consequently, one having ordinary skill in the art would be able to practice Claims 1-4 and 17-21 without undue experimentation. Based on at least these noted reasons, Applicants believe that Claims 1-4 and 17-21 fully comply with the enablement requirement of 35 U.S.C. §112, first paragraph. Accordingly, Applicants respectfully request that the rejection of Claims 1-4 and 17-21 under 35 U.S.C. §112 be withdrawn.

In the Office Action, Claims 1-4 and 17-21 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. In particular, the Office Action alleges that the instant specification fails to teach the claimed genus of polynucleotides encoding a proteins with cysteine protease activity. Applicants respectfully traverse this rejection for at least the reasons set forth below.

The written description for a claimed genus can be satisfied by disclosure of identifying characteristics, including structural and physical characteristics, functional characteristics coupled with known or disclosed correlation with structural characteristics or a combination of such factors sufficient to demonstrate that the applicant was in possession of the claimed subject matter. MPEP § 2163; see University of California v. Eli Lilly, 119 F. 3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). Further, the standard is an objective one, based on what one of skill in the art would recognize in the disclosure. In re Gosteli, 872 F.2d at 1012.

In particular, the Federal Circuit has discussed the application of the written description requirement of the first paragraph of 112 to claims in the field of biotechnology. See University of California v. Eli and Co., 1 19 1559, 43 1398, 1406 (Fed. Cir. 1997). The court explained that:

> In claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate description of the claimed genus . . . a generic statement such as "vertebrate insulin or "mammalian insulin without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is.

The court also stated that "[a]written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by

structure, formula, [or]chemical name, 'of the claimed subject matter sufficient to distinguish it from other materials." at 1567, 43 at 1405. Finally, the court addressed the manner by which a genus might be described. "A description of a genus of may be achieved by means of a recitation of a representative number of defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus."

In the instant application, Applicants have disclosed a polynucleotide (SEQ ID NO: 1) that encodes a protein with cysteine protease activity (SEQ ID NO: 2) (specification at paragraph [0015] – [0018]). This disclosed specie is representative of the claimed genus of polynucleotides that may code for a cysteine protease as represented by SEQ ID NO: 2. The disclosed nucleotide specie encodes a cysteine protease with a conserved cysteine protease active site. It would be clear to one of skill in the art how to modify the disclosed polynucleotide specie (SEQ ID NO: 1) to arrive at a cystein protease as represented by SEQ ID NO: 2. Such modification to the disclosed polynucleotide specie can be purposefully made to retain the active site of the cysteine protease. Accordingly, Applicants respectfully submit that the rejection of Claims 1-4 and 17-21 be withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same.

The Commissioner is hereby authorized to charge deposit account 02-1818 for any fees which are due and owing.

Respectfully submitted,

K&L GATES LLP

BY _____

Robert M. Barrett
Reg. No. 30,142
Customer No. 29157

Dated: June 3, 2009